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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,047

08/26/2003

Bill H. McAnalley

MANN:1003RCE

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12/01/2009

CHALKER FLORES, LLP

2711 LBJ FRWY

Suite 1036

DALLAS, TX 75234

EXAMINER

FRITCHMAN, REBECCA M

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/648,047	<b>Applicant(s)</b> MCANALLEY ET AL.	
	<b>Examiner</b> REBECCA FRITCHMAN	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,8,11-22 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,11-22 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

This is the Final Office Action based on the 10/648047 RCE attorney remarks filed 09/22/2009.

Claims 1, 5, 8, 11-22, & 36 are pending and have been fully considered.

### **Response to Amendment**

2. Previous rejection in view of Fleischner, Brand and Cho have been maintained. This is due to the fact that applicant has provided no proof or explanation as to why their result is "unexpected". Also, applicant has not stated what exactly the unexpected result is. Therefore, the examiner maintains the position that the invention as a whole is obvious and would produce predictable results.

### **Claim Rejections - 35 USC § 103**

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 1, 5, 8, 11-22 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischner (USP 6,291,533) in view of Brand et al. (An Outstanding Food Source of Vitamin C, The Lancet, Vol. 320 Issue 833, p. 873) and further in view of Cho et al. (US Pub 2002/0192314). Fleischner teaches an antioxidant composition comprising a flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, Vitamin C, polyphenols, green tea extract and a carrier such as aloe vera gel extract (columns 7-8).

5. Fleischner teaches a ratio of flavonoid or analog to mixture of vitamin E forms as 40/60 to 90/10 percent by weight (column 8 lines 42-63). In the demonstrated tablet in column 8, the flavonoids equal approximately 245.5 mg, (120 mg Quercetin, 20 mg soy isoflavones, 80 mg silymarin, 7.5 mg flavonoids in Hawthorne berry, 18 mg catechin) and the Vitamin E equals approximately 133 mg. This mixture of flavonoid and Vitamin E forms are present in the composition in a weight ratio of approximately 65/35, respectively, falling into the claimed ratio. While this composition does not teach that the flavonoid and vitamin E forms are present in the composition in an amount of from 30% to 85% by weight, Fleischner teaches using amounts of these that one could use to form a composition with these percentages. Fleischner teaches that Quercetin is a powerful antioxidant that is known to reduce the risk of stroke (column 7 line 36). It would have been obvious for one of ordinary skill in the art to make a tablet

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containing a 30% weight percentage of quercetin and vitamin E forms in order to make a tablet that has a stronger ability to reduce risk of stroke.

6. Fleischner does not teach a source of vitamin C and does not disclose a composition additionally comprising bush plum pulp and skin comprising 5% vitamin C. Brand et al. disclosed in 1982 that bush plum pulp and skin is an outstanding source of Vitamin C (p.873). Thus, one needs only a small amount of this fruit to meet the daily requirements of vitamin C. Adding an ingredient with a high proportion of the nutrient is ideal for nutritional supplements as it keeps the size of the supplement small while adding a higher concentration of the desired ingredient. It would have been obvious for one of ordinary skill in the art to modify Fleischner with the teachings of Brand et al. by using the edible parts of bush plum as the source of vitamin C so as to keep the size of the supplement small while adding enough vitamin C to meet the intended nutritional requirements. While Brand et al. do not teach a percentage of vitamin C of 5% in the edible fruit, it is within the knowledge of one with ordinary skill in the art to modify the percentage of a nutrient in an ingredient for the desired effect.

Fleischner does not disclose a supplement additionally comprising grape skin extract comprising 30-82% polyphenols. Cho et al. teaches a dietary supplement comprising grape skin extract ([0012]) comprising polyphenols of between 25 and 100%, within applicant's disclosed range ([0016]). Grape skin extracts have known antioxidant properties, specifically known to inhibit LDL cholesterol oxidation ([0012]). It would have been obvious to modify the

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teachings of Fleischner by adding grape skin extracts in 25-100% polyphenols order to gain the advantages of the antioxidant properties. Further, it would have been obvious to have grape skin and green tea extracts present in a weight ratio of from 60/40 to 80/20 percent in order to optimize a result-effective variable. The benefits of both are known and it would have been obvious to find the ideal percentage composition of grape skin and green tea in order to maximize the antioxidant benefits of these components. In the absence of unexpected results, the claimed weight ratio would have been obvious to one of ordinary skill in the art.

7. Applicant's arguments with respect to claims 1, 5, 8, 11-22 and 36 have been considered but are moot in view of the new ground(s) of rejection. The Office reviewed the previous rejection and calculated that Fleischner does in fact teach a flavonoidNitamin E mixture in a weight ratio of from 40/60-90/10 percent, thus reading on the instant claims.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F.

/Krishnan S Menon/

Primary Examiner, Art Unit 1797